4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2462]

Workshop to Enhance Clinical Study Diversity; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled "Workshop To Enhance Clinical Study Diversity." This public workshop will satisfy a mandate of the Food and Drug Omnibus Reform Act of 2022 (FDORA) for FDA to convene one or more public workshops to solicit input from various stakeholders on enhancing diversity in clinical studies. The public workshop will be convened and supported by a cooperative agreement between FDA and the Clinical Trials Transformation Initiative and will solicit input from interested parties on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the prevalence or incidence of the disease or condition among demographic subgroups, where appropriate.

DATES: The public workshop will be held virtually on November 29, 2023, from 10 a.m. to 2 p.m., Eastern Time and November 30, 2023, from 10 a.m. to 2 p.m., Eastern Time. Following the workshop, a public comment period will be established to receive comments related to the topics addressed during the public workshop. Either electronic or written comments on this public workshop must be submitted by January 29, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom platform. The link for the public workshop will be sent to registrants upon registration.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time on January 29, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-2462 for "Workshop To Enhance Clinical Study Diversity." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket

number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240-402-8962, Dat.Doan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3603 of the FDORA requires FDA to convene one or more public workshops to solicit input from various stakeholders on increasing diversity in clinical studies. To meet the FDORA requirement, FDA will convene a workshop with key participants, including drug and device sponsors, clinical research organizations, academia, patients and patient advocates, study site investigators, and the public, to gather input on how to enhance clinical study diversity by discussing ways to (1) increase enrollment of historically underrepresented populations in clinical studies and (2) encourage clinical study participation that reflects the prevalence of the disease or condition among demographic subgroups, where appropriate. The public workshop scheduled for November 29, 2023, and November 30, 2023, will fulfill the requirement to convene a public workshop no later than 1 year after the date of the enactment of FDORA.

II. Topics for Discussion at the Public Workshop

At the public workshop, FDA plans to solicit input from participants on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects disease prevalence or incidence data, including but not limited to:

1. The collection and presentation of disease prevalence and incidence data by demographic group

2. The dissemination of information to the public on clinical study enrollment demographic data
3. The establishment of goals for clinical study enrollment, including the relevance of disease prevalence and incidence
4. The approaches to include underrepresented populations and encourage participation that reflects the population expected to use the drug or device, if approved, including:
    A. The establishment of inclusion and exclusion criteria for certain subgroups, such as pregnant and lactating women and individuals with disabilities, including intellectual or developmental disabilities or mental illness
    B. The considerations regarding informed consent with respect to individuals with intellectual or developmental disabilities or mental illness, including ethical and scientific considerations
    C. The appropriate use of decentralized trials or digital health tools, clinical endpoints, biomarker selection, and studying analysis

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: https://duke.zoom.us/meeting/register/tJcrceuhqjgvE9zGjDNOURONoJZvxrpK4Rvi#/registration. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free, and persons interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact Sabrena Mervin-Blake, 919-724-0715, sabrena.mervin-blake@duke.edu no later than November 15, 2023. Please note, closed captioning and American Sign Language will be available automatically.

Dated: August 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.
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